

MMCC GUIDANCE: CLINICAL DIRECTOR REQUIREMENTS

May 2020

Note: Licensed dispensaries will have until September 1, 2020 to comply with the new requirements of COMAR 10.62.31.

The following guidance is provided to assist medical cannabis businesses to comply with state laws and regulations governing the clinical director requirements.

This document is not legal advice. It is meant to assist licensed medical cannabis businesses with understanding the clinical director requirements, and to comply with state laws and regulations. Please consult an attorney if you have any questions regarding the legal requirements that apply.

OVERVIEW

A clinical director for a licensed dispensary <u>may not</u> provide a written certification for medical cannabis to any qualifying patient, pursuant to COMAR 10.62.31.01(E).

- All licensed dispensaries are required to appoint an individual to serve as a clinical director, pursuant to COMAR 10.62.31.
- To be eligible to serve as a clinical director, an individual must:
 - Be eligible to serve as a certifying provider, as defined in Health General Article, §13-3301, Annotated Code of Maryland, or
 - Be a licensed pharmacist in good standing with the State Board of Pharmacy, or
 - Have substantial education, training, and experience in the medical use of cannabis, as determined by the Commission.
- A clinical director's role is to provide education to medical cannabis patients and caregivers, as well as to provide training to dispensary agents.
- A clinical director must be available during hours of operation, and may provide services:
 - On-site at the licensed dispensary, or
 - Be available via electronic communication.

Eligibility to Serve as a Clinical Director

An individual may be eligible to serve as a clinical director if they meet one or more of the following:

- Eligible to serve as a certifying provider, as defined in Health General Article, §13-3301, Annotated Code of Maryland. This means an individual who:
 - 1. Is a physician, nurse practitioner or certified nurse midwife, dentist, podiatrist, or a physician assistant who has an active delegation agreement with a primary supervising physician who is a certifying provider;
 - 2. Has an active, unrestricted licensed to practice in Maryland; and
 - 3. Has a State controlled dangerous substances registration;
- Be a licensed pharmacist in good standing with the State Board of Pharmacy; or

• Have substantial education, training, and experience in the medical use of cannabis, as determined by the Commission.

The Commission will evaluate whether an individual has "substantial education, training, and experience in the medical use of cannabis" on a case-by-case basis. An individual seeking to qualify under this criterion shall at a minimum:

- 1. Be a health care practitioner, as defined in Health Occupations Article, §1-1001, Annotated Code of Maryland; and
- 2. (1) Have a degree or certificate related to the medical use of cannabis; (2) Have completed substantial coursework related to the medical use of cannabis; or (3) Have substantial work experience treating individuals with medical cannabis or educating individuals about the medical use of cannabis.

In order to demonstrate substantial education, training or experience, and individual should submit:

- Transcripts and any other relevant information relating to academic courses, including course descriptions etc.;
- Academic or professional references;
- Relevant certificates or degrees demonstrating completion of course work;
- Curriculum vitae demonstrating professional experience;
- Any additional information requested by the Commission.

The Commission will review all registrations on a case-by-case basis, and may request additional information if needed to evaluate a registration.

Note: A registration based on education, training, and experience in the medical use of cannabis must be reviewed and approved by the Commission. Applicants should anticipate at least 45 days before formal consideration of a clinical director application under this criterion.

Responsibilities of a Clinical Director

Clinical directors are responsible for educating qualifying patients and caregivers in the following areas:

- Potential drug-to-drug interactions, including interactions with alcohol, prescription drugs, non-prescription drugs, and supplements;
- Possible side effects or contraindications of medical cannabis use;
- The potential for differing strengths and effects of medical cannabis strains; and
- Different methods, forms, and routes of medical cannabis administration.

Clinical directors are responsible for training dispensary agents on the following:

- Guidelines for providing information to qualifying patients related to risks, benefits, and side effects associated with medical cannabis;
- Recognizing signs and symptoms of substance abuse; and
- Guidelines for refusing to provide medical cannabis to an individual who appears to be under the influence of drugs or alcohol.

A clinical director must be available during hours of operation, and may provide services:

- On-site at the licensed dispensary, or
- Be available via electronic communication that allows the clinical director to answer questions in real-time.

A clinical director may serve at multiple dispensaries as long as they are able to provide the required services.

Clinical Director Reporting Requirements

Dispensaries must submit a quarterly report related to the Clinical Director's activities to the Commission beginning for the period of October 1, 2020 to December 31, 2020. This report is due to the Commission by January 31, 2021.

The report should include:

- The most frequently asked questions by qualifying patients and caregivers to the clinical director; and
- The responses provided to the most frequently asked questions by qualifying patients and caregivers to the clinical director.

All reports should be submitted to reporting.mmcc@maryland.gov.

The reporting requirement shall remain in effect until July 1, 2022, when it shall terminate and be of no further force and effect.

Training Requirements

All clinical directors must complete at least one Commission-approved training course each year. The clinical director must attest to course completion annually by June 30th. Each licensed dispensary should retain supporting documentation demonstrating the clinical director has completed a Commission-approved training.

As of May 2020, the Commission has approved one training course, which is available at mmcc.maryland.gov. Alternative on-line and in-person training courses may be submitted to the Commission for consideration at reporting.mmcc@maryland.gov.

Training resources for clinical directors

Clinical directors, certifying providers, and other medical professionals interested in learning more about the clinical uses of cannabis may now enroll in an online medical education curriculum developed by TMCIGlobal. The course was designed based on the laws and regulations governing the Maryland medical cannabis program. The two-hour online Maryland course presents the basics of the endocannabinoid system and the pharmacology of cannabis, qualifying conditions and administration methods approved in the state of Maryland, medical cannabis contraindications, and identified adverse effects of cannabis use. It is divided into five lessons, each with knowledge check questions that users can complete at their own pace. The course can be started and stopped as desired, and materials may be revisited as often as needed for the duration of the course access period.

About TMCIGlobal (TMCI):

<u>TMCI</u> provides science-based, online medical education for healthcare professionals who want to learn about medical cannabis and its potential clinical application to deliver quality care and address patient questions. TMCI works with organizations that are recognized as pillars of medical cannabis learning and brings their valuable medical expertise to the healthcare community via an ever-growing online course catalog.

To access the course, please visit: <u>Maryland State Health Care Provider Education Course</u>

Please note: This course is now accredited. Here are the details of the course:

• Duration: 2.5 hours

- 2.5 CME credit available
- Assessment Quiz
- Mobile-friendly

For questions please contact:

TMCI: themedical cannabisinstitute.org

Email: info@tmciglobal.org

Maryland Medical Cannabis Commission: Email: mdh.providerinfo@maryland.gov

Clinical Director Registration

What is the process to register as a clinical director?

Clinical director registration is an online process. The application form must be completed and submitted in one session. You will not be able to save and complete the application at a later time.

1. Complete and submit an online application.

You will need:

- i. A valid, accessible email account
- ii. One of the following accepted forms of eligibility to serve as a clinical director:
 - Maryland Board of Physicians license number and your Controlled Dangerous Substances registration number; or
 - Maryland Board of Pharmacy license number; or
 - Relevant information pertaining to substantial experience, training and education in the medical use of cannabis. **NOTE**: if you are registering based on substantial experience, training and education in the medical use of cannabis, the Commission will evaluate the credentials provided in order to make an eligibility determination.
- 2. Verify your email address. After submitting your application, a verification email will be sent. You must click the verification link in the email message to verify your account. You will receive a follow-up email advising whether your application has been approved by the Commission. Be sure to retain your approval email as it contains your Username and MMCC Clinical Director ID Number.

Renewal and Annual Training Requirement

Your initial registration is valid for two years. Prior to that expiration, you will be notified via email by MMCC that your expiration date is approaching. You will need to ensure any relevant state licensure is in good standing, and then log into the Clinical Director Registry to renew your MMCC registration.

You must also provide an annual attestation by June 30th indicating that you have met the education requirement.

END OF DOCUMENT